CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF PESTICIDE REGULATION
MEDICAL TOXICOLOGY BRANCH

SUMMARY OF TOXICOLOGY DATA
DIATOMACEOUS EARTH

Chemical Code # 195, Tolerance # 1017

October 14, 1992
Revised December 31, 2001

I. DATA GAP STATUS

Chronic toxicity, rat:	No study on file
Chronic toxicity, dog:	No study on file
Oncogenicity, rat:	No study on file
Oncogenicity, mouse:	No study on file
Reproduction, rat:	No study on file
Teratology, rat:	No study on file
Teratology, rabbit:	No study on file
Gene mutation:	No study on file
Chromosome effects:	No study on file
DNA damage:	No study on file
Neurotoxicity:	Not required at this time

Note: In a memorandum dated August 14, 1997, the Office of Environmental Health Hazard Assessment agreed with the Department of Pesticide Regulation that no further studies on diatomaceous earth were required. Therefore, although no adequate studies have been submitted under SB950, no further animal toxicity studies are being required.

Toxicology one-liners are attached.

All record numbers for the above study types through 048466 (Document No. 009) were examined.

This includes all relevant studies indexed by DPR as of December 31, 2001.

In the 1-liners below:
** indicates an acceptable study.
Bold face indicates a possible adverse effect.

File name: T011231
Revised by J. Gee, December 31, 2001

II. TOXICOLOGY ONE-LINERS AND CONCLUSIONS

These pages contain summaries only. Individual worksheets may identify additional effects.

COMBINED, RAT

No study on file.

CHRONIC TOXICITY, RAT

No study on file.

CHRONIC TOXICITY, DOG

No study on file.

ONCOGENICITY, RAT

No study on file.

ONCOGENICITY, MOUSE

No study on file.

REPRODUCTION, RAT

No study on file.

TERATOLOGY, RAT

No study on file.

TERATOLOGY, RABBIT

No study on file.

GENE MUTATION

No study on file.

CHROMOSOME EFFECTS

No study on file.

DNA DAMAGE

No study on file.

NEUROTOXICITY

Not required at this time.

OTHER STUDIES

1017 009 048466 AThe effect of ingestion of diatomaceous earth in white rats: a subacute toxicity test.@ (Bertke, E. M., publ. in: *Toxicology and Applied Pharmacology* 6: 284 - 291 (1964), Arizona State University.) Wistar rats, 15/sex/group, were fed diets containing 0, 1%, 3% or 5% diatomaceous earth for 90 days. The diatomaceous earth was of freshwater origin and contained 85.2% silicon, 3.9% aluminum, 5% sodium, 2% iron and 1% magnesium plus minor or trace elements, mostly in the form of oxides. Ninety percent of the particles were < 0.1 mm with the largest being 0.64 mm. The test material was mixed with feed and made into pellets. Weekly weights were recorded. After 90 days, the animals were sacrificed and organ weights (liver, kidney, spleen) recorded. Selected organs/tissues were examined for histological changes. These included stomach, small and large intestine, liver, kidneys, spleen, lung, urinary bladder, adrenal glands, lymph nodes, testes or ovaries. Results were presented for the control and high dose groups only. Relative organ weights of controls and 5% group were similar. Weight gain was greater in the 5% group. There was no increase in silica in the liver, spleen or kidney. Histological examination showed no difference from control animals, including the fundic region of the stomach. No adverse effect. Unacceptable, not upgradeable (limited parameters). No worksheet. (Gee, 12/21/01).

1017 009 048467 APig study@ (McGill, L. D., Veterinary Reference Laboratory, Inc., Utah, 7/20/79) The purpose was to study the efficacy of diatomaceous earth as an antihelminthic in swine. There were 4 groups of 6 pigs each. Pigs were infected with embryonated eggs of Ascaris. The conclusion of the author was that diatomaceous earth showed some activity as an antihelminthic. Data were insufficient for an independent evaluation. Supplemental study. (Gee, 12/21/01)